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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,297	07/05/2000	Dosuk D. Lee	04712/02000G	2121
21559	7590	12/17/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			LEVY, NEIL S	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/284,297	LEE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Neil Levy	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40,42,43,103,111-143 and 145-153 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40,42,43,103,111-135,138-140,142,143,145-148,150-153, is/are rejected.
- 7) ☒ Claim(s) 136,137,141,147 and 149 is/are objected to.
- 8) ☒ Claim(s) 40,42,43,103,111-143 and 145-153 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 43, 127, 128, 133, 135 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18, 21 of copending Application No. 09/993739.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the rejection of record is maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40, 42, 43, 111-118, 120, 127-131, 133, 134 are rejected under 35 U.S.C. 102(e) as being anticipated by Constant ~~596028~~.

The rejection of record is maintained. Constant ~~596028~~ shows use of carbonated (dahllite, col. 3, lines 12-14) hydroxy apatite (col. 1, 1.) to permit biomedical implantation, without exothermic necrotizing reaction (col. 2, top).

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The reaction products reflect crystal growth inhibition, and X-ray diffraction changes (col. 2, lines 35, 36, 43-56); the instant "poorly crystalline ACP", not further identified in claims. Dry components of calcium phosphate and other, the instant promoter, ca sources (col. 5, line 25-65), are combined (col. 5, last paragraph, top col. 6), mixed and pressed to form a monolithic solid – product (col. 7, lines 38-61; col. 8, top). Lubricant can be added (col. 7, line 55-57). Note the instant claims are in open guise, thus permitting of ~~Constant~~ wet mixing of powders; Neither is the claimed instant process seen as requiring successive steps, rather than combination of procedures ~~Constant~~. Examples show mixing, and ~~mixing~~, meeting the instant compression, since there is no claimed quantification of compression, while ~~Constant~~ (Example 2, table 3) shows compressed products. As to stoichiometry, it is less than 1-5 Ca/P (col. 4, line 61). As to supplemental materials, hyaluronic acid derivatives, collagen is included (line 67, col. 6). Collagen is seen as meeting the requirements instantly claimed of adherence, tensile strength, and elasticity of the composite.

Claims 40, 42, 43, 103, 111-114, 116-121, 124, 126-135, 138-140, 142, 143, 145, 146, 148, 150-153 are rejected under 35 U.S.C. 102(e) as being anticipated by ~~Constant~~ et al 5782971.

See B., Col. 8: A bioceramic of the instant claim 40 is prepared by mixing powders of Ca Phosphate (ACP) with promoters, Ca Carbonate, and supplemental materials, Ca phosphates – The material is then put in a die, thus permitting shape predetermined – that of the die – and compressed (III. A.) and then hydrated after 37° incubation, and products tested for compression Strength

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(col. 9, lines 29 –39). Prosthetic devices and the Bioceramic, bioresorbable products are envisioned. Mixing of dry powders prior to liquid addition is a disclosed variation of the paste preparation (col. 5, line 11-28). The lubricant is water or other physiological lubricant (col. 8, line 28-31). Ca/P is as low (col. 5, lines 5-10) as 0.1 to 1 (less than 1.5) as instantly claimed, inclusive of amorphous Ca P.

ACP and Ca O, or dicalcium phosphate dehydrate are disclosed (col. 4, lines 12-23). A number of supplemental agents to enhance (col. 5, line 50 – line 8, col. 6) characteristics inclusive of resorption time, strength and other desirable properties may include Ca sulfate. The products are bioresorbable, biocompatible, applicable as a paste in vivo (col. 6, lines 11-39), to harden, or can be used as implants, or prosthetic devices (last paragraph, col. 6). Note the paste does not set up, but is injectable, at room temperature (col. 6, line 27-55) and sets at body temperature – thus, endothermic (col. 8, lines 48-50). Active additives are at col. 6, top. Compression strength and pressure at col. 6, line 40-55. Particulate extenders are at col. 6, top – calcium sulfate; Dematerialized bone is matrix Gla – protein. Claims 150, met, at col. 6 lines 47-50, and, since same components are those instantly utilized, at the same compression strength, so would the density, as of claim 151.

Claims 40, 42, 43, 103, 111-118, 120-123, 125, 127-131, 133, 134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constant - 5962028.

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Constantly~~2~~ is seen as obvious, since, as indicated above, Constantly~~2~~ uses the instant components, mixed as powders, with lubricant fluids added to provide wet mixing, or added after mixing, followed by compression. There is no preclusion of the instant language of fluid with powder, since the instant language is in open guise, thus obvious over the same steps of Constantly~~2~~ regardless of when each step is performed, since the outcome, the product, is the same in each case.

Claims 42, 118, 133 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Please see duplicate language of claim 42; polyanhydrides. Also, it is unclear if copolymers are of poly (anhydride-co-imide) only, or of all the afore stated polymeric components. Finally, the supplemental material is seen as any one of the components or compounds listed; the claim does not require one of bioresorbable and one of non-bioresorbable. If this is an incorrect reading, please amend to clarify. Claim 40 recites powdered promoter, but claims 118, 133. Claim 133 includes phosphorous acid liquid.

Applicant's arguments filed on 8/24/04 have been fully considered but they are not persuasive. Applicants arguments maintain that powders are compressed, not liquid containing. We fail to see why liquids can't be with the powders given no language indicating a dry mix excluding liquids, or using "consisting of" powder. The other issues of missing components or compounds, have been addressed in the rejections above. The remaining issue of powder

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mix, compression, and hydrating is also addressed in rejection above, and as met by applicant's claims interpretable as broadly read in open claim Language to permit of the process steps in any order. Applicant's arguments, in view of amendment, as convincing, have resulted in the withdrawal of some rejections, while an updated search fails to provide further teachings of some aspects of applicant's inventive composites and methods.

Claims 126, 137, 141, 147, 149 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (571) 272-0619. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gray Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Levy/LR  
December 3, 2004



NEIL S. LEVY  
PRIMARY EXAMINER